

PTO/SB/21 (08-06)

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| TRANSMITTAL FORM (to be used for all correspondence after initial filing) | Application Number | 09/606,370 | RECEIVED CENTRAL FAX CENTER OCT 23 2006 |
| | Filing Date | October 3, 2001 | |
| | First Named Inventor | Holmes et al. | |
| | An Unit | 1645 | |
| | Examiner Name | V. Portner | |
| | Attorney Docket Number | 33,363-00 | |
| Total Number of Pages in This Submission | | 4 | |

| ENCLOSURES (Check all that apply) | | |
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| <input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input checked="" type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below): |
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| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT | | | |
|--|---------------------|----------|--------|
| Firm Name | Howson & Howson LLP | | |
| Signature | <i>Mary E. Bak</i> | | |
| Printed name | Mary E. Bak | | |
| Date | 10-23-2006 | Reg. No. | 31,215 |

| CERTIFICATE OF TRANSMISSION/MAILING | |
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| Typed or printed name | Summer Uchin |
| Date | 10-23-2006 |

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33,383-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 09/806,370 Confirmation No.: 8568
Applicant : Holmes et al.
Filed : October 3, 2001
TC/A.U. : 1645
Examiner : V. Portner
Customer No. : 00270
Title : MUTANT CHOLERA HOLOTOXIN AS AN ADJUVANT

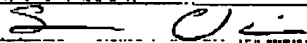
Mail Stop Appeal - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT UNDER 37 CFR § 41.33

Sir:

This paper is filed after the Notice of Appeal, but prior to the Appeal Brief, and is to reduce the issues for appeal. Specifically, this paper is filed to cancel subject matter added to the specification by way of the Amendment and Response filed on July 12, 2004. Appellants are requesting deletion of the sequence listing and the phrase "SEQ ID NO: 1" on page 38, lines 7-34. These specification amendments moot the outstanding new matter rejection under 35 USC § 132(a). These amendments were not presented earlier since the Declaration, which at that time of filing, was believed to be fully compliant, but was not entered by the Examiner for assertedly being defective.

Amendments to the Specification begin on page 2.

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AMENDMENTS TO THE SPECIFICATION

Amend the paragraph on page 38, lines 7-34, according to the following:

The antigenic compositions of this invention also comprise CT-CRM containing at least one additional mutation at a position other than at amino acid residue 29. International application WO 93/13202 (36), which is hereby incorporated by reference, describes a series of mutations in the A subunit which serve to reduce the toxicity of the cholera holotoxin. These mutations include making substitutions for the arginine at amino acid 7, the aspartic acid at position 9, the arginine at position 11, the histidine at position 44, the valine at position 53, the arginine at position 54, the serine at position 61, the serine at position 63, the histidine at position 70, the valine at position 97, the tyrosine at position 104, the proline at position 106, the histidine at position 107, the glutamic acid at position 110, the glutamic acid at position 112, the serine at position 114, the tryptophan at position 127, the arginine at position 146 and the arginine at position 192. The nucleotide sequence encoding the A subunit of the cholera holotoxin is set forth in International application WO 93/13202 (~~SEQ ID NO: 1~~). International application WO 98/42375 (37) which is hereby incorporated by reference, describes making a substitution for the serine at amino acid 109 in the A subunit, which serves to reduce the toxicity of the cholera holotoxin. Therefore, using conventional techniques, mutations at one or more of these additional positions are generated.

Please delete the two (2) page sequence listing.

33.383-00

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or during the pendency of this application, or credit any overpayment in any fees to our Deposit Account No. 08-3040.

Respectfully submitted,

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